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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,971	05/02/2002	Nils Brunner	99999.000309	2813

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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/030,971	BRUNNER NILS	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,31-44,48,50,57 and 58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,31-44,48,50,57 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Non-Final Office Action

Claims 28, 31-44, 48, 50, 57 and 58 are pending. No claim is allowed. Amendments are entered. This application is a 371 of PCT/DK00/00406.

Invention: Method of use of the extract of Actaea racemosa, syn. Cimicifuga recemosa (Black Cohosh).

Summary of this Office Action dated Sunday, May 13, 2007

1. Continued Examination under 37 CFR 1.114
2. Information Disclosure Statement
3. Copending Applications
4. Specification
5. 35 USC § 112 --- First Paragraph Written Description Rejection
6. 35 USC § 112 --- First Paragraph Scope of Enablement Rejection
7. 35 USC § 102(b) Rejection
8. 35 USC § 103(a)-
9. Communication
10.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/26/2007 has been entered.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 USC § 112 --- First Paragraph Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 31-44, 48, 50, 57 and 58 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply:

There is no support for example in claim 28 for "symptoms associated therewith in a woman" wherein the woman has breast cancer, has had breast cancer, or has a risk of developing breast cancer". Furthermore, claim 50 is drawn to a method according to claim 28, wherein the composition is combined with a drug, which has a selective estrogen receptor modulating (SERM) activity.

Applicant had no possession of the claimed invention at the time of filing this application. Applicant is kindly requested to explain the issue.

Specification does not contain the treatment of estrogen deficiency conditions including dermatological disorders such as ageing of the skin, dryness of mucous membranes (e.g. vaginal and intestine), brain related disease such as Alzheimer's including other types of dementia, bone and joint related disease such as osteoporosis, osteochondrosis, osteo-arthritis, rheumatoid arthritis, healing of bone fractures, and reduce in skeletal fractures and disease such as hyperlipidaemia, hypercholesterolaemia, arteriosclerosis, etc. in the subgroup of women who are currently suffering from breast cancer, who have a prior history of breast cancer, or women with an increased risk of developing breast cancer.

Present claims

Claim 28. A method of treating a estrogen deficiency in a woman and ~~who suffers from breast cancer, or has a ri~k of recurrent breast cancer, or has a ri~k of developing breast cancer, wherein said woman demonstrates~~ symptoms associated therewith in a woman, of estrogen deficiency, the method comprising administering ~~tot~oman,~~ a composition comprising ~~an extract of~~ Cimicifuga racemosa, or an aqueous or an alcoholic extract thereof, wherein the woman has breast cancer, has had breast cancer, or has a
risk of developing breast cancer said extract obtainable by vortexing Cimicifuga racemosa material in an aqueous solution.

Claim 31. A method according to claim 28, wherein the composition has an estrogen-like effect which manifests itself in the composition being capable of inducing an increase in uterine weight in adult ovariectomized NMRI female athymic nude mice.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See *In re Kaslow*, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or

specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech,* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

See MPEP 2163.06 (for Applicant's convenience relevant portion is as follows):

GENERAL PRINCIPLES GOVERNING COMPLIANCE WITH THE "WRITTEN DESCRIPTION" REQUIREMENT FOR APPLICATIONS

The first paragraph of 35 U.S.C. **112** requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). >See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description").< The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what

the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., >*Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, **>323 F.3d 956, 969-70,< 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. **132**. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, i.e., whether that party can "make the claim" corresponding to the interference count. See, e.g., *Martin v. Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987). In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980)

(original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem*, **>323 F.3d at 963<, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR **1.801** *et seq.*

A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Enzo Biochem*, **>323 F.3d at 968<, 63 USPQ2d at 1616 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. **119**, **120**, or **365(c)**. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under **35 U.S.C. 119**, **120**, or **365(c)** (see, e.g., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); Fiers v. Revel, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

2163.06 Relationship of Written Description Requirement to New Matter

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one

of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter. There are two statutory provisions that prohibit the introduction of new matter: **35 U.S.C. 132** - No amendment shall introduce new matter into the disclosure of the invention; and, similarly providing for a reissue application, **35 U.S.C. 251** - No new matter shall be introduced into the application for reissue.

Claim Rejections - 35 USC § 112—Scope of enablement

Claims 28, 31-44, 48, 50, 57 and 58 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of breast cancer by using *Cimicifuga racemosa* extract, does not reasonably provide enablement for the **method for treating an estrogen deficient women has a** *risk* of developing breast cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use of the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount

of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention

Presently claimed invention is drawn to a method for treating which are caused by estrogenic deficiency (claim 28). There is no support for the methods of claims 28, 31-44, 48, 50, 57 and 58 as they are drawn to a method for treating an estrogen deficient women who suffers from breast cancer or has a risk of developing breast cancer, wherein said women demonstrates symptoms of estrogenic deficiency.

The predictability or unpredictability of the art:

There is no support for how the diseases such as "brain related disease", "a bone and joint related disease" (claim 43) can be successfully treated. In claim 34 citation of "wherein the estrogen like effect processed by the composition manifests itself in the composition being capable of inducing a lowering in FSH and LH in a woman" is not supported in specification. Similarly in claim 35 the support of "wherein the estrogen like effect possessed by the composition manifests itself in the composition being capable of inducing an estrogen like change in vaginal cytology in a woman". Invention as claimed couldn't be predicted seeing the results presented in the disclosure.

In WO 98/50026 discloses the treatment or prevention of menopausal symptoms and osteoporosis by using isoflavone. See for menopausal symptoms lines 10-28 on page 1; lines 1-14 on page 2; and examples. There is nothing about any symptoms related to such as "brain related diseases" as has been presently claimed. It is therefore, unpredictable by seeing the disclosure of the present invention.

There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Therefore predicting the method of treating, curing and The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. >See, e.g., *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1326 (Fed. Cir. 2004) ("Nascent technology, however, must be enabled with a 'specific and useful teaching.' The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no knowledge independent from the

patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology."

The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. In particular, the court in *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-70 (CCPA 1971), stated:

[I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof.

The scope of the required enablement varies inversely with the degree of predictability involved, but even in unpredictable arts, a disclosure of every operable species is not required. A single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements. *In re Vickers*, 141 F.2d 522, 526-27, 61 USPQ 122, 127 (CCPA 1944); *In re Cook*, 439 F.2d 730, 734, 169 USPQ 298, 301 (CCPA 1971). However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. See MPEP 2164.03.

relieving by using "steroidal estrogen" is impossible. There are more than thousands of known steroidal estrogens.

The amount of direction or guidance presented

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim

will possess the alleged activity. See *In re Riat* et al. (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr et al. (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result".

See *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

The presence or absence of working examples

There no examples or test data in vivo or in vitro to support all the methods as presently claimed.

The quantity of experimentation necessary

Since the nature of the method is so unpredictable, and since the claims are drawn the method for treating an estrogen deficient women has a *risk* of developing breast cancer and since there is a lack of guidance present in the specification, the

skilled artisan would have to undertake undue experimentation to practice the claimed invention commensurate with the scope of the claims.

The instant claims are drawn to the method for symptoms of estrogen deficiency (claim 28). The specification lacks guidance and examples as to how one of ordinary skill in the art at the time of invention would utilize the claimed method of treating the estrogen deficiency in woman and the risk associated with in a woman using extracts of *Cimicifuga racemosa* wherein the woman has the breast cancer, has had breast cancer, or has a risk of developing breast cancer.

In order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would have go through undue experimentation to use the invention as presently claimed without further guidance. Specification does not teach how all the methods as presently claimed can used successfully for such treatments as claimed.

35 U.S.C. 102(b)--Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 28 is rejected under 35 U.S.C. 102(b) as being anticipated by NESSELHUT et al[1]. The prior art discloses a pharmaceutical composition and method for treatment of breast cancer, comprising an effective amount of extract of Cimicifuga (SP-001) and an effective amount of at least one antiestrogenic compound, which discloses the presently claimed invention. See the entire document especially lines 40-67 in col. 2, summary of invention, examples, and figure. See line 15 in col. 4 where human breast cancer line was used for the least. Furthermore, the reference discloses the treatment for "the patient generally will be in need of the treatment when suffering from a neoplastic or pre-neoplastic disease (lines 49-56 in col. 3.

The prior art discloses: "The effect, according to the invention, of the Cimicifuga extract on the proliferation of estrogen-dependent carcinoma cells, in particular mammary carcinoma cells, was determined in vitro using a test system of MCF 7 cells. The MCF 7-cell line is an established in-vitro model for estrogen-dependent tumors, which possess both estrogen receptors and aromatase activity. The human breast cancer cell line was derived from a pleural effusion associated with a metastasizing mammary tumor and possesses significant quantities of 17.beta receptors (Schwarte, A. (1994) Wirkspektrum ausgewahlter Flavonoide auf die humane Brustkrebslinie MCF-7: Eine in vitro Studies [Activity spectrum of selected flavonoids on the human breast cancer cell line MCF 7: An in-vitro study]. Witten-Herdecke, University, Field of Medicine, Dissertation 1994). The effect of Cimicifuga extract on the proliferation of the

[1] United States Patent No. 6,267,994 B1. See the entire document.

MCF 7 cells were determined by measuring the incorporation of radioactively labeled thymidine."[2]

The reference discloses, "In one embodiment, composition comprising an extract of a medicinal plant of the genus Cimicifuga is administered to a patient---", see lines 10-15 in col. 2.

Response to Arguments

- Previous rejection is maintained, as arguments are not found persuasive.

Nesselhut et al. teaches the treatment when suffering from a neoplastic or pre-neoplastic diseases see lines 48-55 in column 3.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

[2] Lines 9-67 in col. 4.

more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER